

DETAILED ACTION

Applicant's amendment and argument of 2/1/10 are entered.

Claims 15 and 43 are amended.

Claims 48 has been cancelled.

Claims 9, 15, 16, and 40-46 are presently pending and considered.

Claim Status, Cancelled Claims

In light of the cancellation of Claim 48, all rejections and/or objections to such claim are rendered moot, and thus, are withdrawn.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 15, 16, and 40-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

Applicant's claims are drawn to methods of delivering any protein to a lymphnode, by transforming macrophages local to the lymphnode with a transgene encoding any protein with a

secretion signal, the macrophages draining the lymphnode, and thereby expressing the encoded protein, the protein being secreted, and thereby delivered to the lymphnode.

The specification appears to discuss utilities of inducing immune responses (e.g., pp. 3-4, paragraph bridging), modulating an immune system (p. 4, paragraph 2), and eliminating cells in a lymphnode (pp. 4-5, paragraph bridging). The encoded proteins are required to be those that induce an immune response, modulate an immune system, and cytotoxic proteins, in each case (pp. 3-5). However, Applicant's claims are in no way limited to these types of cells, and simply require any protein. Hence, these utilities do not need to be considered for the patentable utility. Further, Applicant's examples are simply drawn to the use of a specific protein, which is used to represent the enabled invention for the Artisan. The specific protein, however, is GFP however, and the experiments are only for demonstrating that the protein can be delivered. There is nothing about what the result is which has an enabled, patentable, utility.

On the other hand, the only well-known utility commensurate with the claims is to deliver the protein to the lymph node to determine what happens. Such, however, is not specific, and is generic to delivery to any tissue and use of any protein. Moreover, it is not substantial as it is a utility which is self-determining, i.e., it is scientific exploration. In other words, in each instance, the various proteins would be expressed, then the Artisan would have to find out what happens, then find out what to do with the product obtained.

Therefore, Applicant's claimed invention does not meet the utility requirement.

Claims 9, 15, 16, and 40-46 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and

credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

To wit, because the Artisan would have determine what to do with the obtained object, the invention is not enabled for its use, as such would be inventing Applicant's claimed invention for Applicant. Such is undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection has been modified in light of the finding that Applicant knew that the Artisan knew, prior to Applicant's priority date, that IM injection would lead to transformed macrophage cells which would drain to the lymph.

Claims 9, 15-16, and 40-46 are newly rejected, under 35 U.S.C. 103(a) as being unpatentable over US PAT APP NO 2004/0063652 to Jolly; Stacey, et al. (1996) Journal of Immunology, 157: 2116-22; Kataoka, et al. (1997) J. Biol. Chem., 272(29): 18209-15; US PAT NO 5,783,567 to Hedley, et al.; Samlowski, et al. (1988) Regional Immunology, 1(1): 41-55; US PAT NO 5,763,416 to Bonadio, et al.; Roitt, et al. "Immunology" [Textbook] (1985), Published by Gower Medical Publishing, Ltd., London, England, several pages excerpted, pp. 1-1 to 1-6, 2-10 to 2-13, and 3-1 to 3-9; Yamanaka, et al. (1993) Avian Diseases, 37(2): 459-66 (ABSTRACT ONLY); Cantini, et al. (1995) Journal of Neuropathology and Experimental Neurology, 54(1):

121-28; Kadir, et al. (1992) *International Journal of Clinical Pharmacology, Therapy, and Toxicology*, 30(1): 374-82 (ABSTRACT ONLY); Gopalakrishnakone, et al. (1984) *Toxicon: The Official Journal of the International Society on Toxinology*, 22(1) 85-98; Beresford, et al. (1957) *British Journal of Pharmacology*, 12: 107-114, and as further emphasized by Chattergoon, et al. "Specific Immune Induction Following DNA-Based Immunization Through In Vivo Transfection and Activation of Macrophages/Antigen-Presenting Cells", *The Journal of Immunology* (15 June 1998), 160(12): 5707-18.

Jolly teaches the use of plasmids (e.g., paragraph 0037) to effect the transformation of macrophage cells, to effect killing (e.g., paragraphs 0067-71) and for general secretion of proteins that block pathogenic interactions local to the cell (paragraph 0155), which requires secretion signals. Jolly also teaches that getting the vector to be expressed in a target lymph node is desired (e.g., paragraph 056, indicating the targeting of a particular lymph node is a desirable feature). Lastly, Jolly teaches bupivacaine as an additive to enhance transfection (paragraph 0365).

Still further, with regard to the possibility that Jolly is randomly teaching the use of plasmids and it is not enabled, Stacey teaches that plasmids are taken up by macrophages and transgenes are expressed (e.g., Figure 6). Hence, the Artisan knows specifically that macrophages will pick up plasmids and express the transgenes therein.

Kataoka teaches the human CD156 gene, and its promoter sequence as specific for macrophage expression, as well as the structure of such promoters (p. 18215).

Hedley teaches the transformation of macrophages of the draining lymph nodes by subcutaneous injection (e.g., col. 8, paragraph 3), and Samlowski teaches that macrophages were

known to drain to the lymph nodes local to the site of injection (e.g., ABSTRACT), hence, macrophages drain locally and not distantly.

Bonadio teaches that the SV40 polyA signal is a standard signal for termination of transcripts (e.g., EXAMPLE IX).

Roitt provides a very detailed understanding of the flow of monocytes to sites of injury and to the lymph nodes to be recirculated. Specifically, it is noted that page 3-8 provides Figure 3.24 which demonstrates that lymphocytes travel through the peripheral tissues, to lymph nodes, and then into several possible locations, one of which is to return to the peripheral tissues. Further, it is noted that page 1-4 demonstrates that macrophages flow specifically out of the circulatory system (the blood) into damaged tissues (last paragraph). Further, it is noted that monocytes can migrate out of the blood to the site of injury and differentiate into more macrophages (p. 1-3, paragraph bridging columns). Still further, it is noted that it is well known that the whole body contains a lymph node network, to circulate the various lymphocytes back to the thoracic duct, and nodes are known to be located throughout, as well as particularly at branches of the lymphatic vessels (p. 3-4). Hence, the Artisan knows that the macrophages will drain to the lymph nodes. Still further, Roitt teaches that the antigens are processed in the lymph nodes for immune responses (e.g., pp. 3-4 to 3-7).

Moreover, as further evidence that macrophages are found as a response to muscle tissue damage, Yamanaka, Cantini, Kadir, Gopalakrishnakone, and Beresford each demonstrate that as far back as 1957, it was well known that macrophages respond to tissue damage in muscle by migrating to the damage site (See the ABSTRACTs of each article).

From the confluence of this, it is clear that Jolly teaches transfection of macrophages *in vivo* with plasmids, Hedley and Samlowski teaches that transformation of the macrophages will lead to transfected macrophages in the draining lymph nodes, Roitt demonstrates that the Artisan understands the circulation of Macrophages and that they circulate through all tissues, Yamanaka, Cantini, Kadir, Gopalakrishnakone, and Beresford demonstrate that the macrophages are specifically attracted to the site of muscle tissue damage, and Kataoka and Bonadio teach the required signals for expression of a gene in macrophages.

Still further, Chattergoon teaches that plasmids injected intramuscularly will transform macrophages which will express the transgene and drain the lymphnode local to the site of injection (p. 5716, col. 2, penultimate paragraph).

Further, when injecting substances, it is standard in the Art to administer substances which numb the area to avoid hurting the subject. One such substance which was well known in the Art is Bupivacaine

(http://www.drugdigest.org/DD/DVH/Uses/0_3915_7903%7CBupivacaine%2BHCL.00.html).

Such if further noted, in Jolly, to be a compound to use for IM injection and will enhance free DNA expression, which is, absent reason to believe otherwise, occurring through enhancing transfection (See portion discussing Jolly, ABOVE). Hence, the further administration of Bupivacaine was well known in the Art for such use, and as such the further utilization of Bupivacaine would be obvious.

Therefore, at the time of invention, the method would have been obvious. The Artisan would be motivated to choose a site local to the lymph node target, which will be intramuscular, depending on which lymph nodes are being targeted (it is well known in the Art that lymph

nodes are located throughout the body and near muscle) because the macrophages were known to drain to local lymph nodes. One such motivation is to produce proteins delivered to the lymph node, which provides for more immunologic processing. Still further, the Artisan would inject the plasmid by IM injection in order to deliver it to a lymph node local to the muscle injection site, via the understood attraction of macrophages like in Hedley and Samlowski, but to muscle, as is shown in Roitt's understanding of migration of macrophages, and the teachings of Yamanaka, Cantini, Kadir, Gopalakrishnakone, and Beresford, which show that macrophages migrate to the site of damage in muscle tissue. Still further, the administration of Bupivacaine to a subject during or prior to injection of the vector would be motivated in order to avoid pain in the subject due to administration. Moreover, the Artisan would have expected success, as the transformation of macrophages was already known and the draining of such macrophages to lymph nodes was well known in the Art. In addition, the obtained result would necessarily be obtained as the macrophage is secreting the protein.

Lastly, it should be noted that the references for IM administration are not required for Claims 40, 41, 42, 43, and 44, as these claims encompass at least subcutaneous injection.

Response to Argument – obviousness

Applicant's argument of 2/1/10 has been fully considered but is not found persuasive.

Applicant argues that the Office's finding in reopening prosecution that the issue of whether or not macrophages drain to the local lymph, and the issue of whether or not the macrophages drain then to the local lymph nodes, is not what Applicant is arguing. What Applicant states that they have been arguing is whether or not the Artisan would be motivated to

choose a site local to the lymph node target because macrophages were known to drain to the local lymph nodes. (p. 7, first full paragraph-p. 8, paragraph 1.)

Such is not persuasive. It appears that the argument is whether or not the Artisan would be motivated to choose a lymph node, then find a site local to such lymph node for injection of the nucleic acid. The Examiner is thankful that this issue is somewhat clarified for prosecution's sake. Applicant themselves actually did demonstrate that transformation of macrophages occur after IM-injection of plasmid, and the macrophages did then drain to the lymph while expressing the gene on the vector (e.g., Chattergoon, et al. "Specific Immune Induction Following DNA-Based Immunization Through In Vivo Transfection and Activation of Macrophages/Antigen-Presenting Cells", The Journal of Immunology (15 June 1998), 160(12): 5707-18, p. 5716, col. 2, penultimate paragraph), and therefore, it seems clear that Applicant understands that macrophages may be transformed by IM injection of plasmids, and that they express transgenes from the plasmids, and that they drain to the local lymph nodes while expressing the transgenes. Hence, Applicant's argument seems to be clear that they believe the step of choosing the lymph node into which to drain is non-obvious, as the Artisan would not be motivated to choose such. In response, the Examiner argues that if the aforementioned knowledge of transformation, draining into the lymph nodes local to the site of IM injection, and expression of the transgene, are known, then the Artisan, being a capable person, having a Ph.D. or M.D. would necessarily be able to apply such knowledge to utilize the method to target a specific lymph node. It should be noted however that Applicant's other arguments again argue what Applicant presently has said is not of issue.

Applicant argues that the Art cited by the Examiner does not support an obviousness rejection, references utilized teach away from the claimed invention, and the combination of references do not provide the Artisan with a reasonable expectation of success. Further, issue taken with the previous arguments utilization of the exact wording of "combined knowledge". Further averisons are provided, but again, each are conclusory. (p. 8, paragraphs 2-5.)

Such is not persuasive. The argument is conclusory and does not demonstrate where the errors are, but concludes they are there. There is nothing to argue.

Applicant argues that none of the references teach the step of identifying a lymph node as a target for protein delivery, and locating a site proximal to the lymphnode (p. 8, last paragraph).

Such is not persuasive. With regard to identifying a lymph node, the context of the rejection is taken within the skill of the Artisan. The simple question is whether the Artisan, who knew what would happen, could then extrapolate the known phenomena to then predetermine which lymph node was to be used, and then inject a site local to such lymph node. The Examiner maintains that the Artisan is quite capable of doing so.

Applicant argues that none of the references teach that "free" DNA would be taken up and expressed by macrophages, and the macrophages drain to the lymph nodes (pp. 8-9, paragraph bridging).

Such is not persuasive. As is cited now, in the Chattergoon reference, it is clear that Applicant themselves had informed the Artisan that the free DNA administration would have the same result. To argue against such, without citing this Article to the Examiner, appears to question the good faith of Applicant. If Applicant is aware of something that is critical to the

Arguments but does not make it of light, especially when it disagrees with Applicant's stance on an argument, is not proper. Good faith requires full disclosure. While the Examiner will not at this time notify the Office of this evidence, as it may be that Applicant and Applicant's representative have not noticed this deficiency, future evidence which indicates possible misbehavior will be reported, along with the current evidence. **Again, to be clear, Applicant will not make arguments which are not commensurate with what they know to be true.**

Applicant argues that the Jolly references disclose expressing a protein a macrophage by use of a vector that comprises a macrophage promoter driving expression of the protein. However, it is argued that Jolly does not disclose how to administer such vector, nor to choose a lymph node local to the site of administration (p. 9, paragraph 2).

Such is not persuasive. Jolly is utilized to provide general motivations to a lymph node and deliver a protein to it. The rejection is under obviousness, not anticipation. Moreover, the rejection is taken within the context of the skill of the Artisan.

Applicant argues that the Hedley references teaches "microparticles" and not free DNA, and hence, it teaches away from free DNA (p. 9, paragraph 3).

Hedley is utilized in a rejection under obviousness. Hence, even if Hedley did not teach the free DNA, the other references still supply the required subject matter. However, Hedley teaches that the microparticles are administered, and *release DNA from the microparticle, which released free DNA which is taken up is free DNA* (DETAILED DESCRIPTION OF THE INVENTION, paragraph 1). Hence, free DNA is what is taken up, and hence, free DNA can be administered, as is shown by the other references.

Applicant argues that Hedley is limited to subcutaneous injection for uptake, and hence, does not teach IM administration (p. 9, paragraph 5).

Such is not persuasive. Applicant's claims encompass subcutaneous administration, the other references, including Applicant's own disclosure in the prior art, teach IM administration, and the Hedley reference is not taken out of context and alone. Clearly, Hedley only increases the knowledge that Macrophages may be targeted by subcutaneous injection at the least, which is encompassed by the broad claims. Moreover, Applicant should note that a "teaching away" is a teaching against, not a teaching that other things may be used, or preferred.

Applicant argues that Stacey only teaches uptake of plasmids *in vitro* and hence, is not reasonably predictable for *in vivo*. (p. 10, paragraph 1).

Such is not persuasive. Applicant's own Chattergoon reference makes up for any perceived deficiency.

Applicant broadly argues differences between *in vivo* and *in vitro* (p. 10, paragraph 2).

Such is not persuasive. The argument is mooted by Applicant's own prior Art disclosure that it would work.

Applicant argues that Hedley teaches away from free DNA (p. 10, last paragraph).

Such is not persuasive. First Hedley teaches the free DNA to be form taken up (argument *supra*), and Applicant's own disclosure already taught the artisan that it would work.

Applicant argues that the Artisan would not combine references to arrive at the benefits of the invention (p. 11, paragraphs 1-2).

Such is not persuasive, as it is simply conclusory. Moreover, any aversions are overcome by Applicant's own prior Art disclosure.

Applicant argues that the cited references do not indicate IM injection would result the delivery (p. 11, paragraph 3).

Such is not persuasive. Applicant's own prior Art disclosure teaches such at the very least.

Applicant argues that the specification teaches it is surprising that the free DNA is not degraded (p. 11, paragraph 4).

Such is not persuasive. Applicant's own prior Art disclosure teaches that the transgene is expressed.

Applicant argues that the deficiencies are not made up for with the various other references, and specifically that Kadir teaches away as NS was found to be irritating (p. 12, paragraph 1).

Such is not persuasive. Kadir does not teach away from this, because NS is very distinct from a biological molecule like DNA. Moreover, Applicant's own prior Art disclosure teaches that the transgene is taken up and expressed. Applicant's extrapolation from a toxic drug like NS being specifically discussed as to its free form, to something else, which is not such a toxic drug, seems to defy the logical understanding of the Artisan. Applicant is requested to elaborate, perhaps with a declaration to demonstrate the Artisan understood all compounds are exactly the same in free form.

Applicant argues that Gopalakrishnakone is not related and provides nothing to the rejection (pp. 12-13, paragraph bridging).

Such is not persuasive. The reference clearly supports the knowledge that the Artisan knew that the macrophages are specifically attracted to the site of muscle tissue damage. If

Applicant disagrees, a declaration with supported evidence to demonstrate that the Artisan would not have understood Gopalakrishnakone to support such, along with the other references, is invited. Peicemeal argument is not correct in an obviousness rejection.

Applicant argues, similar to the Gopalakrishnakone reference, that Cantini does not support a rejection (p. 13, paragraph).

Such is not persuasive. The same response is provided.

Applicant argues Beresford in kind with Cantini and Gopalakrishnakone, then argues that the iron is permanently fixed, so it does not drain to the lymph (p. 13, paragraph 2).

Such is not persuasive. The same response is provided. In addition, Beresford's disclosure that Applicant argues is tangential to the teaching which was utilized. The macrophages are still there, aren't they? If not, again, a declaration to demonstrate what the Artisan would have known is suggested.

Applicant again argues that they have taught the method, and the Artisan would not have known the macrophages could be transformed, express the protein, and drain the lymph node, to thus deliver the protein (pp. 13-14, paragraph bridging).

Such is not persuasive. Applicant's own added disclosure clearly shows that the Artisan knew the various processes would take place, and the skill of the Artisan is such that he or she could choose the lymph node to target, and site local, which may be IM. Hence, although this may be the first exact disclosure, it is still obvious.

Applicant argues that a rationale is not provided as to why to perform the method (p. 14, paragraph 2).

Such is not persuasive. Jolly provides the general motivation to deliver proteins to the lymph nodes. Therefore, the method is a general tool in the arsenal the biological chemist may use to deliver the protein.

Applicant argues that the Examiner is "picking and choosing" those elements required for the rejection, and the Office is not allowed to pick and choose elements, while ignoring the rest of the documents disclosures (p. 14, last paragraph).

Such is not persuasive. Picking and choosing may be done, so long as the references do not teach against it. Here, there is nothing to argue it will not work.

Applicant argues that although Jolly teaches targeting lymph nodes, it does not teach doing so in the same manner (p. 15, paragraph 1).

Such is not persuasive. Jolly teaches the motivation to target a lymph node. That is what is motivation. The arguments to the rest of the reference appears to be non-essential to the motivation which is provided. To argue that Jolly is limited to being in the context of itself is wrong. The Artisan is still aware of what he or she is aware of. Jolly has made the Artisan aware of the motivation to target a lymph node. Lastly, as far as *In re Fine*, the definition of "deprecate" is to belittle something, not to utilize information for an obviousness-type rejection. It is recommended that Applicant carefully read their quotations for context and meaning, as such seems to be reoccurring problem. Misquotations and taking things out of context only lead to further distrust, given Applicant's history of arguing against things they have already informed the Artisan about.

Applicant argues that Roitt in context with Jolly does not work, as Jolly teaches other methods of delivery (pp. 15-16, paragraph bridging).

Such is not persuasive. The context of joining references does not require the Artisan to be limited in all aspects to the other reference. What is required, for an obviousness rejection is to demonstrate the Artisan understood that they could utilize the various claimed elements to derive at the invention. Hence, this specifically does useful elements of the prior Art to be pieced together from the prior art, as long as nothing teaches against it.

Applicant again argues Stacy is limited to *in vitro* (p. 16, paragraph 2).

Such is not persuasive. Applicant's own prior art disclosure has put into possession of the Artisan the same subject matter.

Applicant argues that identification of a lymph node to which muscle attracted lymph nodes drain is not proper (p. 16, penultimate paragraph).

Such is not persuasive. Applicant's claims do not require a specific lymph node be identified, to the exclusion of other lymph nodes. Moreover, the other interpretation is still also rejected as the Artisan knew the lymph node proximal is the one that macrophages drain into.

Applicant argues that the choice of lymph node is not inherent, as Jolly teaches targeting a lymph node, but uses a vector, and does not utilize a macrophage (pp. 16-17, paragraph bridging).

Such is not persuasive. First, Applicant's own prior art informed the Artisan of the draining to local lymph nodes, with free DNA transformed macrophages, *in vivo*. Second, Jolly teaches that targeting a lymph node is an object desired by the Artisan. So, it does necessarily flow that to target a lymph node, the node must be chosen to which to target.

Applicant argues that Roitt cannot be read in isolation of its other teachings (p. 17, penultimate paragraph).

Such is not persuasive. There is nothing in Roitt that teaches against the method found obvious.

Applicant cites *In re Gurley* to argue that the disparaging of results is not what "teaching away" means (p. 18, paragraphs 1-2).

Such is not persuasive. Applicant's own quoted statement from Gurley teaches "if it suggests the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Applicant". Hence, this is the disparaging which is discussed. There is nothing in the references to demonstrate the method to be unlikely to be productive of the result of delivering a protein into the lymph node.

Applicant argues other arguments to the point that Examiner is confused as to what is being said (p. 18, last paragraph).

Such is not persuasive. While the Examiner does not understand, it does appear to be an admission that Applicant misstated something, but the second part however, maintains the rejection is improper because the office has not shown that the references would yield the claimed invention, and with a reasonable expectation of success (p. 18, last paragraph). The Examiner maintains for this, that the rejection is correct, especially in light of Applicant's own prior art disclosure.

Applicant argues hindsight reconstruction, picking and choosing references, and then ignoring context, to provide an incorrect rejection (p. 19, first paragraph).

Such is not persuasive. All construction is hindsight, as it must find the various elements. However, to arrive at such, the Examiner has simply combined the knowledge already present in

the Art to arrive at a method which utilizes each portion for its known function. There is nothing incorrect about this, as nothing teaches against it.

Applicant broadly argues that the rejection is incorrect, even though having 12 references (p. 19, paragraph 2).

Such is not persuasive. The rejection now has 13 references, if Applicant's count is correct. However, it is correct, And was correct. The new reference is utilized because it's Applicant's own prior art disclosure, and speaks to much of the core subject matter, and argues against Applicant's own arguments.

Applicant argues that it was known that proteins expressed from transfected cells at a damaged site are delivered to lymph nodes local to the site (p. 19, penultimate paragraph).

Such is not persuasive, especially given Applicant's own prior art disclosure.

Applicant broadly argues they are the first to do the method, and demonstrate it works, and it was not obvious (pp. 19-20, paragraph bridging).

Such is not persuasive. The invention is obvious as it simply puts together knowledge already in the Art. Further, Applicant's own prior disclosure teaches Applicant's own arguments throughout, and emphasizes much of what is argued to be non-obvious.

For these reasons, the rejections are held, with addition of Applicant's own prior Art.

CONCLUSION

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Robert M Kelly/
Primary Examiner of Art Unit 1633